



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-332]

Listing of Noroxymorphone in the Code of Federal Regulations and Assignment of a Controlled Substances Code Number

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: Noroxymorphone is a derivative of opium and opiates and, as such, is a schedule II controlled substance. The Drug Enforcement Administration (DEA) has established the use of the Drug Enforcement Administration Code Number 9668 for tracking noroxymorphone and for establishing aggregate production quotas. This rule amends the Code of Federal Regulations (CFR) to reflect the current practice of using the Code Number 9668 for noroxymorphone. This rulemaking will list the schedule II controlled substance noroxymorphone as a basic class with the Code Number 9668. This rule does not affect the control of noroxymorphone as a schedule II controlled substance.

DATES: Effective: [INSERT DATE OF PUBLICATION].

FOR FURTHER INFORMATION CONTACT: Lynnette Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 598-8837

SUPPLEMENTARY INFORMATION: Noroxymorphone is a schedule II controlled substance defined in the Controlled Substances Act (CSA) by 21 U.S.C. 812(c), Schedule

II (a)(1) and 21 CFR 1308.12(b)(1), which control “opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.” It meets the statutory definition of a “narcotic drug” as stated in 21 U.S.C. 802(17) as it can be obtained from the chemical modification of substances extracted from vegetable origin, specifically from the plant species *Papaver somniferum* L. that is lawfully defined as “opium poppy” by 21 U.S.C. 802(19). It is not an isoquinoline alkaloid, which is categorically excluded from the statutory definition of a “narcotic drug.” 21 U.S.C. 802(17)(A). Rather, noroxymorphone is a phenanthrene alkaloid with a similar chemical structure to other opium and opiate phenanthrene alkaloids listed in 21 CFR 1308.12(b)(1), such as hydrocodone, hydromorphone, dihydroetorphine, ethylmorphine, etorphine hydrochloride, metopon, thebaine, morphine, codeine, oxycodone, and oxymorphone. Noroxymorphone meets the statutory definition of “opiate” as it can be readily converted to other morphine-like substances including oxymorphone, which has an addiction-forming or addiction-sustaining abuse liability similar to morphine. Based on the similarity of the chemical structure of noroxymorphone to opium alkaloids listed in 21 CFR 1308.12(b)(1), and the fact that it is obtained by the chemical modification of these listed opium alkaloids, noroxymorphone is a derivative of opium and opiates and a schedule II controlled substance as defined by 21 U.S.C. 812(a)(1) Schedule II and 21 CFR 1308.12(b)(1).

As provided in 21 CFR 1308.03, each controlled substance or basic class thereof is assigned a four digit Drug Enforcement Administration Controlled Substances Code Number that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, DEA uses these Code Numbers in

establishing aggregate production quotas for basic classes of controlled substances listed in schedules I and II as required by 21 U.S.C. 826.

Since 1996, DEA has established an aggregate production quota for noroxymorphone using the DEA Controlled Substances Code Number 9668. In this final rule, DEA is amending the CFR to reflect the current practice of using the DEA Controlled Substances Code Number 9668 for noroxymorphone. Listing noroxymorphone and its DEA Controlled Substances Code Number in 21 CFR 1308.12(b)(1) does not alter the status of noroxymorphone as a Schedule II controlled substance. Noroxymorphone already is included as a Schedule II controlled substance because 21 CFR 1308.12(b)(1) controls any salt, compound, derivative, or preparation of the listed substances. Accordingly, noroxymorphone has been controlled as a derivative of the listed substances and this rule will not result in adding any new substances into the schedules. Listing noroxymorphone also will not affect the aggregate production quota currently established. DEA-registered manufacturers of noroxymorphone previously granted individual quotas for such purposes may continue to apply for quota after this rule is finalized.

Regulatory Analyses

Administrative Procedure Act (APA).

Under 5 U.S.C. 553(b)(3)(B), an agency may dispense with notice and comment rulemaking when, for good cause, it “finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures because the inclusion of noroxymorphone and its DEA Controlled

Substances Code Number in the list of schedule II substances in 21 CFR 1308.12(b)(1) is “a minor or merely technical amendment in which the public is not particularly interested.”’ *National Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79-752, at 200 (1945)). See also *Utility Solid Waste Activities Group v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001) (the “unnecessary” prong “is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public”) (int. quotations and citation omitted). This rule is a “technical amendment” to 21 CFR 1308.12(b)(1) as it is “insignificant in nature and impact, and inconsequential to the industry and public.”

Similarly, the APA states that a rule cannot be made effective less than 30 days after publication, unless the rule falls under one of three enumerated exceptions. One of these exceptions is when an agency provides good cause that compliance would be impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(d)(3). A delayed effective date for this rule is unnecessary because this rule simply lists the schedule II controlled substance noroxymorphone in 21 CFR 1308.12(b)(1) as a basic class and assigns to it the DEA Controlled Substances Code Number 9668. This rule merely amends the CFR to reflect the current DEA business practice and better assist companies in complying with registration and quota requirements. In addition, this rule does not require those firms that handle noroxymorphone to alter their current practices with respect to their quota applications and reporting obligations.

For the reasons stated above, notice and comment procedures are unnecessary and this rule may be made effective upon publication.

*Executive Order 12866, 13563, and 13771, Regulatory Planning and Review,
Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling
Regulatory Costs*

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders 12866 and 13563. This rule is not a significant regulatory action under Executive Order 12866. Noroxymorphone is a derivative of opium and opiates and, as such, is a schedule II controlled substance. In this final rule, DEA is merely amending its regulations to reflect the current practice of using the DEA Controlled Substances Code Number 9668 for noroxymorphone. Listing noroxymorphone and its DEA Controlled Substances Code Number will not alter the status of noroxymorphone as a Schedule II controlled substance. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

Because this final rule is not significant under Executive Order 12866, it is not subject to the requirements of Executive Order 13771.¹

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

¹ Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled “Reducing Regulation and Controlling Regulatory Costs” (Feb. 2, 2017).

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As explained above, the DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

This rule does not impose a collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Congressional Review Act (CRA), 5 U.S.C. 804. Pursuant to the CRA, the DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Drug traffic control, Controlled Substances.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.12 is amended by redesignating paragraphs (b)(1)(x) through (xviii) as paragraphs (b)(1)(xi) through (xix), respectively, and by adding a new paragraph (b)(1)(x) to read as follows:

§ 1308.12 Schedule II.

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(1) * * *

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(x) Noroxymorphone.....9668

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Dated: August 5, 2019.

Uttam Dhillon,

Acting Administrator.

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